February 14, 2007

Centers for Disease Control and Prevention

Important Information Regarding Intussusception and RotaTeq® Vaccine

The Food and Drug Administration (FDA) has notified health care providers and consumers about reports of intussusception following administration of Rotavirus, Live, Oral, Pentavalent vaccine (trade name RotaTeq®), manufactured by Merck and Co., Inc. (www.fda.gov/cber/safety/phnrota021307.htm) FDA has issued this notification to encourage the reporting of any additional cases of intussusception that may have occurred or will occur in the future after administration of RotaTeq®. The number of intussusception cases reported to date after RotaTeq® administration does not exceed the number we would expect to occur without vaccination. Although the data we have received so far suggests that RotaTeq® does not cause intussusception, it is possible that because of incomplete reporting of cases to VAERS and other factors, some increased risk of intussusception associated with RotaTeq® vaccination could yet be found. Thus, CDC and FDA are continuing to carefully monitor reports of possible adverse effects of the vaccine.

KEY FACTS

- We are not surprised by the number of reported intussusception cases following RotaTeq vaccination.

- Intussusception, a form of bowel obstruction, occurs spontaneously in the absence of vaccination. There are a number of intussusception cases that occur every year in children in the age group recommended for RotaTeq® (6-32 weeks of age) and are not related to the vaccine.

- The number of intussusception cases reported to date after RotaTeq® administration is consistent with the number of cases we expected to see based on background rates in unvaccinated children.

- These cases were detected through routine monitoring of a new vaccine using the Vaccine Adverse Event Reporting System (VAERS). This routine monitoring is done to ensure the safety of all vaccines. We are closely monitoring VAERS reports for this vaccine as we would with any newly licensed vaccine. However, we are aware of past issues with rotavirus vaccine and intussusception and,

therefore, we will continue to closely watch for cases of intussusception following rotavirus vaccination.

- This notice does not mean there is a problem with the RotaTeq® vaccine. CDC is not changing its policy at this time. CDC continues to support the Advisory Committee on Immunization Practices' recommendation for routine immunization of all U.S. infants with three doses of RotaTeq® administered orally at ages 2, 4 and 6 months. (www.cdc.gov/nip/publications/acip-list.htm)

- This report will be discussed at the February 21-22 ACIP meeting.

- CDC and FDA encourage all healthcare providers and other individuals to report any cases of intussusception or other severe adverse events to the Vaccine Adverse Event Reporting System. For a copy of the vaccine reporting form, call 1-800-822-7967 or report online to www.vaers.hhs.gov

Questions About RotaTeq and Intussusception

What is rotavirus?

Rotavirus is a virus that causes severe diarrhea, vomiting, fever and dehydration (gastroenteritis) in infants and young children. It is the leading cause of gastroenteritis in infants and children worldwide.

Each year in the United States, rotavirus is responsible for more than 400,000 doctor visits; more than 200,000 emergency room visits; 55,000 to 70,000 hospitalizations; and between 20 and 60 deaths. In developing countries, rotavirus is a major cause of childhood deaths, estimated to cause more than half a million deaths each year in children less than 5 years of age.

What is RotaTeq® vaccine?

RotaTeq® vaccine is the only vaccine approved in the United States for prevention of rotavirus disease. Licensed in 2006, RotaTeq® is the best way to protect your child against rotavirus disease. Studies indicate that RotaTeq® will prevent about 74 percent of all rotavirus cases and about 98 percent of the most severe cases, including 96 percent of cases requiring hospitalization.

Is this the same vaccine for rotavirus that was taken off the market because of problems?
No, this is not the same vaccine. In 1999, RotaShield®, a different rotavirus vaccine, was withdrawn from the market after it was found to be associated with a type of bowel obstruction called intussusception.

What is intussusception?
Intussusception is a serious, life-threatening condition that occurs when the intestine or bowel becomes blocked. One portion of the intestine telescopes into a nearby portion, causing the obstruction. This leads to inflammation, swelling and eventually decreased blood flow. With prompt detection and treatment, almost all patients fully recover. Although persons of any age can get intussusception, it is most common among infants in the first year of life. Each year, approximately 1,400 U.S. infants less than 12 months of age are hospitalized for intussusception. These cases occurred every year before use of any rotavirus vaccines in the United States.

Has the association between the new RotaTeq® vaccine and intussusception been studied in clinical trials?
Yes. The risk of intussusception for RotaTeq® was evaluated prior to licensure in a large clinical study involving more than 70,000 children. In that study, there was no association found between RotaTeq® and intussusception. Now that the vaccine is being broadly administered, CDC and FDA continue to monitor RotaTeq® for problems in those who receive the vaccine.

How are CDC and FDA monitoring RotaTeq®'s safety?
Following licensure and general use of RotaTeq® and other vaccines in the United States, safety is closely monitored by the FDA and CDC through the Vaccine Adverse Event Reporting System (VAERS). These agencies monitor and evaluate all reports of intussusception and other side effects reported to VAERS.

In addition, CDC is conducting a large study to rapidly detect any association between RotaTeq® and intussusception as well as other potential adverse events through its Vaccine Safety Datalink (VSD). The VSD evaluates vaccine safety in approximately 90,000 infants born each year. Merck and Co., the vaccine's manufacturer, will conduct a separate post-licensure study of approximately 44,000 children.

Are all adverse events reported to VAERS caused by vaccines?
No. It is important to know that many adverse events reported to VAERS may not be caused by vaccines. Reports to VAERS may be submitted by anyone, including healthcare providers, patients and family members. Because of this, VAERS is subject to several limitations including inaccurate reporting and incomplete information.

VAERS receives reports of many events that occur after immunization. Some of these events may occur coincidentally following vaccination, while others may actually be caused by vaccination. The fact that an adverse event occurred following immunization is not conclusive evidence that the event was caused by a vaccine. Factors such as medical history and other medications taken near the time of the vaccination must be examined to determine if they could have caused the adverse event.

Does the available data since RotaTeq® has been on the market indicate that the vaccine is associated with intussusception?
No. Since its licensure on February 3, 2006, until January 31, 2007, CDC and FDA through VAERS have received 28 reports of intussusception 0-73 days following RotaTeq® vaccination. Half of these cases – 14 – occurred within 21 days following vaccination. The number of intussusception cases reported to date after RotaTeq® administration does not exceed the number we would expect to occur without vaccination. Although the data we have received so far suggests that RotaTeq® does not cause intussusception, it is possible that because of incomplete reporting of cases to VAERS and other factors, some increased risk of intussusception associated with RotaTeq® vaccination could yet be found. Thus, CDC and FDA are continuing to carefully monitor reports of possible adverse effects of the vaccine.

Have the recommendations regarding RotaTeq® vaccination changed?
No. This notice does not mean there is a problem with the vaccine. The Advisory Committee on Immunization Practices has not made any changes to the RotaTeq® vaccination guidelines, and CDC is not changing its policy at this time. ACIP recommends routine immunization of all U.S. infants with three doses of RotaTeq® administered orally at ages 2, 4 and 6 months. ACIP will discuss this report at its February meeting.

It is important to remember that the known benefits of the vaccine in preventing rotavirus disease – the cause of one of our most common and potentially severe childhood illnesses – far outweigh any known risks to date.

How can I report any serious side effects following vaccination with RotaTeq® or other vaccines?
Adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting System, which is administered by CDC and the FDA. For a copy of the vaccine adverse event reporting form, call 1-800-822-7967, or report online at www.vaers.hhs.gov.